

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATURAL ALTERNATIVES
INTERNATIONAL, INC., *et al.*,

Plaintiffs,

v.

VITAL PHARMACEUTICALS, INC., and
DNP INTERNATIONAL CO., INC.,

Defendants.

C.A. No. 09-626 (GMS)

VITAL PHARMACEUTICALS, INC.,

Counterclaim/Third-Party Plaintiff,

v.

NATURAL ALTERNATIVES
INTERNATIONAL, INC., and COMPOUND
SOLUTIONS, INC.,

Counterclaim/Third-Party Defendants.)

COMPOUND SOLUTIONS, INC.,

Third-Party Plaintiff,

v.

DNP INTERNATIONAL CO., INC.,

Defendant.

**ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS.
5,965,596; 6,172,098; AND 6,426,361**

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 5,965,596 (the “‘596 patent”); 6,172,098 (the “‘098 patent”); and 6,426,361 (the “‘361 patent”):¹

1. The term “dietary supplement” will not be construed because it is not a limitation.²
2. The term “beta-alanine” is construed to mean “beta-alanine in the form of the individual amino acid, or as a component of a dipeptide, an oligopeptide, or a polypeptide, or an active derivative thereof.”³

¹ The three patents-in-suit are from the same patent family and appear to have the same specification. (See D.I. 74 at 2, n. 2.) Therefore, the court will use the singular form of specification and refer to the ‘361 patent specification.

² A threshold issue is whether a term located in a claim’s preamble is a limitation that must be construed. “In general, a preamble limits the invention if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim. Conversely, a preamble is not limiting ‘where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.’” *Catalina Mktg. Int’l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal citations omitted). Here, the court finds that the term “dietary supplement,” which only appears in the preamble of various claims, is not a limitation requiring construction. Interestingly, this term appears in the preambles of claims in which the body contains the same exact language as the body of claims that have “composition” in the preamble. (See, e.g., ‘361 patent, claims 1 and 5; claims 10 and 17; and claims 22 and 27.) At first glance this may make it seem like the term must be a limitation. On closer examination, however, the principles articulated by the Federal Circuit are not satisfied. In particular, there is no evidence that the patentees used this term to distinguish prior art. See *Catalina Mktg. Int’l*, 289 F.3d at 808 (“[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.”). Also, the specification does not demonstrate that the term was a necessary and defining aspect of the invention. See *On Demand Mach. Corp. v. Ingram Indus.*, 442 F.3d 1331, 1343 (Fed. Cir. 2006) (“In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim.”). In fact, the specification simply notes that the claimed “composition *can be* a dietary supplement.” (‘361 patent, col. 3, l. 41 (emphasis added).) For these reasons, the court agrees with the defendants that the term “dietary supplement” is not a claim limitation requiring construction.

³ Here, the patentees acted as their own lexicographer in defining the disputed term and that lexicography governs. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005). Contrary to the plaintiffs’ contentions, given the unambiguous nature of the patentees’ definition, the court need not apply the analysis set forth in the *Genentech* case. But see *Genentech Inc. v. Wellcome Found.*, 29 F.3d 1555, 1563-64 (Fed. Cir. 1994) (“These diverse definitions reflect either inartful drafting, a conscious attempt to create ambiguity about the scope of the claims, or a desire to claim a wide variety of materials not described or enabled in the specification.”). Moreover, the court agrees with the defendants that, based upon an examination of the prosecution history as a whole, prosecution disclaimer has not been established in this case. See *Storage Tech. Corp. v. Cisco Sys.*, 329 F.3d 823, 833-34 (Fed. Cir. 2003). Thus, the court adopts the defendants’ proposed construction, except for the parenthetical “such as carnosine.” The court could not find a compelling reason to inject (no pun intended) the parenthetical into a definition clearly established by the patentees. (See ‘361 patent, col. 2, ll. 42-46.) Furthermore, as indicated in the specification, and well known to one of ordinary skill in the art, dipeptides include carnosine. (See ‘361 patent, col. 2, ll. 1-2.)

3. The term “L-histidine” is construed to mean “L-histidine in the form of the individual amino acid, or as a component of a dipeptide, an oligopeptide, or a polypeptide, or an active derivative thereof.”⁴
4. The term “unit dosage form” is construed to mean “doses of a certain serving size that can be taken all at once, or in multiple parts throughout the day.”⁵
5. The term “providing an amount of [beta-alanine or L-histidine] to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in a human tissue” is construed to have its plain and ordinary meaning.⁶
6. The term “increasing a concentration of insulin in the blood or blood plasma” is construed to have its plain and ordinary meaning.⁷
7. The term “active derivative” is construed to mean “a compound derived from, or a precursor of, the substance that performs in the same or similar way in the body as the substance, or which is processed into the substance and placed into the body.”⁸

⁴ See footnote 3.

⁵ The court rejects the defendants’ construction because there is no intrinsic support for it. The intrinsic record, however, does support the plaintiffs’ construction. See, e.g., ‘361 patent, col. 3, ll. 46-49; col. 5, l. 56 - col. 6, l. 3; and col. 6, ll. 6-10.

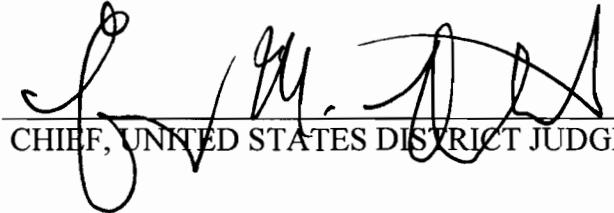
⁶ The court rejects the plaintiffs’ construction because it appears to impose additional limitations. As the defendants’ emphasized at the *Markman* hearing, “there is no limitation on the way that the providing step occurs.” (Tr. at 102:12-13.) Indeed, the specification merely states that the “providing steps of the methods can include ingestion or infusion (e.g., injection) of a composition . . . or a combination of ingestion and infusion.” (‘361 patent, col. 3, ll. 10-13.) There is no indication in this disputed claim language that the providing step is so limited. In fact, to the contrary, the patentees explicitly specified when the providing step includes “ingestion of a composition” (‘596 patent, claim 7; ‘098 patent, claim 7) or “infusion of a composition” (‘596 patent, claim 8; ‘098 patent, claim 8). “Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Phillips*, 415 F.3d at 1316.

⁷ Again, the court rejects the plaintiffs’ construction, which appears to impose additional limitations. The specification states that the “methods can include increasing a concentration of insulin in the blood or blood plasma. The concentration of the insulin can be increased, for example, by injection of insulin.” (‘361 patent, col. 3, ll. 14-16.) The disputed claim term, however, is not expressly limited. The court is persuaded by the defendants’ argument that it should not add limitations specifying mechanisms when the claim only addresses effect. (Tr. at 109:24-110:3.)

⁸ The court adopts the defendants’ construction. The patentees explicitly defined the term “active derivative.” (See ‘361 patent, col. 2, ll. 46-49.) Therefore, the patentees’ lexicography governs. See *Phillips*, 415 F.3d at 1316.

8. The term “mixture” is construed to mean “a composition, physical combination, or blend of substances that are not chemically bonded to one another.”⁹

Dated: May 31, 2011


CHIEF, UNITED STATES DISTRICT JUDGE

⁹ The parties agreed upon this construction prior to the *Markman* hearing as represented in their joint claim chart. (See D.I. 74 at 13.)